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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,516	02/07/2001	Wei-Yu Lo	12875-002001 / 0643-5299U	3185

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08/24/2002

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EXAMINER

PAPPU, SITA S

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/778,516	LO ET AL.	
	Examiner	Art Unit	
	Sita Pappu	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-14 are pending in the instant application. This Office Action is in response to the Amendment filed by the Applicant in paper # 9 on 04/25/2002 and the formal drawings filed in Paper #13 on 06/24/2002. Claims 1-14 are under consideration.

#### ***Response to the amendment***

Claims 1, 4, 5, 9, 11-14 are amended. Currently, claims 1-14 are under consideration.

Drawings submitted in Paper #13 (06/24/2002) have been approved.

The objection to claims 9 and 11 has been withdrawn in light of Applicants' amendment.

The double patenting rejection of claims 7 and 8 has been withdrawn in light of Applicants' amendment.

The rejection of claims 9 and 11 under 35 U.S.C. 112, first paragraph, for biological deposit requirement has been withdrawn in light of Applicant's amendment.

The rejections of claims 1 step (d), 4, 11, 13, and 14 under 35 U.S.C. 112, second paragraph have been withdrawn in light of amendments filed.

The rejection of claims 1-14 under 35 U.S.C. 103(a) has been withdrawn in light of Applicant's amendment and arguments.

Claims 1 and 13 stand rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. Claims 2-12 and 14 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement.

Claim 1, step (b) stands rejected under 35 U.S.C. 112, second paragraph.

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Claims 12 and 14 are rejected under 35 U.S.C. 112, second paragraph.

***Response to Arguments***

In response to the rejection of claim 1 under lack of enablement, Applicant argues (pages 5 and 6, bridging paragraph) that the specification teaches the insertion of a gene, which in this case is the  $\beta$ -galactosidase gene into a vector and that it is applicable to the insertion of any desired gene into an expression cassette (page 6, second paragraph, line 6) and supports the arguments with cited references that teach the insertion of genes such as cyclin A.

Applicant further argues (pages 6 and 7, bridging paragraph) that without the teachings in the specification, a skilled person in the art would also know how to make and use any non-antibiotic resistance gene and its control promoter at the time the application was filed. Applicant cites 3 references that teach the use of non-antibiotic resistance genes.

These arguments have been considered but are not found persuasive and claim 1 stands rejected and claims 2-14 are rejected for reasons of record discussed in the previous Office Action mailed 11/27/2001 (paper # 7) and as discussed below.

As conveyed in the previous Office Action, claims 1-12 and 14 are enabled for use only with  $\beta$ -galactosidase gene as the non-antibiotic resistance gene because, the only use for the Lac shuttle vector of the instant invention, as disclosed in the specification, is as a vaccine carrier. In light of the disclosed use, the specification should teach how any non-antibiotic resistance gene can be used in a contemplated use as a vaccine carrier.

In response to the Applicant's argument that the specification teaches the insertion of a gene, which in this case is the  $\beta$ -galactosidase gene into a vector and that it is applicable to the insertion of any desired gene into an expression cassette, Applicant is reminded that the  $\beta$ -galactosidase gene used comes under the purview of the "non-antibiotic resistance gene" element of the Lac shuttle vector claimed, and not under the purview of "heterologous or desired" gene. With respect to the latter, the only guidance provided is the contemplation in the specification to insert "suitable antigenic genes derived from pathogens or cancers" (page 10, lines 10-13) to obtain "a gene vaccine carrier" which is the only use disclosed. The scope of claims 1-12 and 14 is not limited to the use of antigenic genes but encompasses any gene for the disclosed purpose. However, the specification fails to teach how any gene can be inserted into the Lac shuttle vector of the instant invention, and used as a vaccine.

Thus, the specification is not enabling for the insertion of any gene and any non-antibiotic resistance marker gene into the Lac shuttle vector of the instant invention.

With respect to the rejection of claim 13 under 35 U.S.C. 112, first paragraph, for lack of enablement, Applicant argues that the rejection appears to be or should have been made under lack of asserted utility, and that if reasonably correlated to the particular therapeutic utility, data generated in vitro will be sufficient to establish such a utility (page 7, bottom two paragraphs).

Applicant is directed to the MPEP at section 2164.07, part II, which states that:

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“In some instances, the use will be provided, but the skilled artisan will not know how to effect that use. In such a case, no rejection will be made under 35 U.S.C. 101, but a rejection will be made under 35 U.S.C. 112, first paragraph. As pointed out in *Mowry v. Whitney*, 81 U.S. (14 Wall.) 620 (1871), an invention may in fact have great utility, i.e., may be “a highly useful invention,” but the specification may still fail to “enable any person skilled in the art or science” to use the invention. 81 U.S. (14 Wall.) at 644”.

Further, to support the asserted utility, Applicants submitted a declaration under 37 C.F. R. 1.132 showing immunization of mice with an AFP-expression Lac shuttle vector (page 8, first paragraph).

In response, the Applicant is reminded that no utility rejection has been made for claim 13. While it is a credible utility to use the Lac shuttle vector of the instant invention as a vaccine, the asserted utility is not enabled by the specification and/or the prior art for the reasons of record and as discussed below.

The declaration submitted under 37 C.F.R. 1.132 was fully considered. However, it was not found persuasive because claims are directed to the use of any gene in the Lac shuttle vector of the invention and AFP is not considered enabling for the full scope of the claimed invention, which encompasses any desired gene and is not considered enabling for all antigenic genes. Further, the specification does not contemplate using the AFP gene in the Lac shuttle vector of the instant case, and thus does not provide specific teachings for carrying out the experiments described in the declaration.

As discussed in the previous office action, the purpose of constructing the Lac vector is to use it as DNA vaccine carrier (see specification, page 2, paragraph 2; page 3, paragraph 4; page 10, paragraph 2) by inserting DNA encoding antigens of pathogens and cancer in the eukaryotic expression cassette of the said vector which, when administered to organisms, is expected to generate a protective immune response to a particular antigen and to prevent disease in organisms.

The specification does not provide an enabling disclosure for the prevention of any and all diseases by administering the said Lac vector. In particular, the specification fails to provide sufficient guidance as to the level and character of immune responses required to achieve a prophylactic effect on any and all diseases. At the time of filing the art recognized that while many immunization strategies using specific antigens were capable of generating an immune response against the particular antigen, few were capable of generating a protective immune response against infections or diseases associated with the immunizing antigen.

Therefore, based on the lack of guidance in the specification as to the level and character of immune responses required to achieve a prophylactic effect on any and all diseases using the instant methodology, the art recognized unpredictability of protecting against any and all diseases, particularly HIV and cancer, using gene therapy, and the breadth of the claims, it would have required undue experimentation for the skilled artisan at the time of filing to practice the full scope of the instant invention as claimed in claim 13.

***New Grounds of Rejection***

Claims 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12, step (b) is indefinite in its recitation of "a host cell which". Insertion of "in" after "a host cell" such that the phrase would recite "a host cell in which" is suggested.

Claim 12, step (b) is indefinite in its recitation of "gene thereof is not capable of producing a normal enzymatic function". It is not clear how a gene can produce a function. Use of claim language such as "gene is disrupted" or "gene is non-functional" is suggested.

Claim 14, step (ii) is indefinite in its recitation of "conditions which lactose". Insertion of "in" after "conditions" such that the phrase would recite "conditions in which lactose" is suggested.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone



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numbers for the organization where this application or proceeding is assigned are (703) 308 4242 for regular communications and (703) 872 9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

S. Pappu  
August 23, 2002

*Anne-Marie Baker*  
ANNE-MARIE BAKER  
PATENT EXAMINER